Reference number(s)
2372-A

Specialty Guideline Management

NINLARO (ixazomib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Ninlaro is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

B. Compendial Uses
1. Multiple Myeloma
   a) In combination with lenalidomide and dexamethasone as primary therapy for active (symptomatic) myeloma or disease relapse after 6 months following primary induction therapy with the same regimen
   b) In combination with dexamethasone for patients who have received at least one prior therapy for previously treated myeloma for relapsed or progressive disease
   c) In combination with dexamethasone and pomalidomide for patients who have received at least two prior therapies including an immunomodulatory agent and a proteasome inhibitor and who have demonstrated disease progression on or within 60 days of completion of the last therapy for previously treated myeloma for relapsed or progressive disease
   d) In combination with cyclophosphamide and dexamethasone for patients who have received at least one prior therapy previously treated myeloma for relapsed or progressive disease or for patients who are transplant candidates
   e) As maintenance therapy for transplant candidates with symptomatic myeloma after response to primary myeloma therapy or response or stable disease following autologous stem cell transplant

   *Refer to Section II, Criteria for Initial Approval, for additional approvable multiple myeloma regimens
2. Systemic light chain amyloidosis
3. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple Myeloma

Authorization of 12 months may be granted for treatment of multiple myeloma when any of the following criteria is met:
1. Ninlaro is prescribed in combination with lenalidomide and dexamethasone
2. Ninlaro is prescribed in combination with dexamethasone for patients with relapsed or progressive disease
3. Ninlaro is prescribed in combination with pomalidomide and dexamethasone for patients who have received at least two prior therapies
4. Ninlaro is prescribed as single agent maintenance therapy for transplant candidates
5. Ninlaro is prescribed in combination with cyclophosphamide and dexamethasone for patients who have received at least one prior therapy or are a transplant candidate

B. Systemic Light Chain Amyloidosis

Authorization of 12 months may be granted for treatment of relapsed or refractory systemic light chain amyloidosis.

C. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma when Ninlaro is prescribed in combination with rituximab and dexamethasone.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Ninlaro [package insert]. Cambridge, MA: Takeda Pharmaceutical Company Limited; November 2016.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 2, 2020.